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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------------|
| 10/556,658 | 11/11/2005 | Gary Rheinheimer | 38484-079 (BYRK-24) | 8559 |
| 28524 | 7590 | 11/16/2007 | | |
| SIEMENS CORPORATION INTELLECTUAL PROPERTY DEPARTMENT 170 WOOD AVENUE SOUTH ISELIN, NJ 08830 | | | EXAMINER PAJOOHI, TARA S | |
| | | | ART UNIT 2886 | PAPER NUMBER |
| | | | MAIL DATE 11/16/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/556,658 | Applicant(s) RHEINHEIMER ET AL. | |
| | Examiner Tara S. Pajoochi | Art Unit 2886 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 November 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/11/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. Applicant cooperation is required in correcting any errors of which applicant may become aware in the specification.

Claims 1-30 are pending in this application.

Information Disclosure Statement

2. Acknowledgement is made that the information disclosure statement filed on 11/11/2005 has been received and considered by the examiner. If the applicant is aware of any prior art or any other co-pending applications not already of record, he/she is reminded of his/her duty under 37 CFR 1.56 to disclose the same.

Specification/Drawings

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
4. The disclosure and drawings are objected to because of the following informalities:
 - a. Page 7, paragraph 38, line 1, refers to optical inspection machine "100" in figure 2, however examiner believes it should be figure 1.
 - b. Page 9, paragraph 43, line 7, reagent pad is referred to as reference character "50", however examiner believes it should be "150".
 - c. Page 10, paragraph 48, lines 1-2, refers to figures 4 and 5 with a readhead as reference character "300" however, "300" is not in either of these figures.

Appropriate correction is required.

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. It is unclear whether figures 2-5 are meant to be prior art. They are referred to in paragraph 36 in the section labeled "Detailed Description of Exemplary Embodiments". However they are referred to as to "provide background information." If they are meant to be prior art, please include that in the "Brief Description of the Drawings" as well as labels in the drawings such as -PRIOR ART--.

7. If this is the case, corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

8. Claim 17 recites the limitation "the verification apparatus" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 1, 7, 11 and 17-19** are rejected under 35 U.S.C. 102(b) as being anticipated by **Howard (EP Pub. # 0 837 320)**.

11. Considering **claim 1**, Howard discloses (col. 4-12) and shows in figures 1-3, an apparatus for verifying proper operation of an optical inspection machine, comprising: a row of colored segments that simulate reagent pads containing known types of analytes at known concentrations (i.e., absorbent layers of material impregnated with reagents in specific locations referred to as test fields on the reagent test strip (22, fig. 2) that takes place as an indication of the presence and/or concentration of analyte in the test fluid, col. 4,

lines 22-34), wherein the row of colored segments are positioned so that segments can be illuminated by the readhead (34, fig. 3) of the optical inspection machine (10, fig. 1).

12. Considering **claim 7**, Howard discloses (col. 4, lines 8-34) shows in figure 2, the row of colored segments (i.e., absorbent layers of material) are provided on an insert (22) secured to a housing (20).

13. Considering **claim 11**, Howard discloses (col. 5, line 44 – col. 6, line 9) and shows in figure 2, the colored segments include non-white colored segments separated by white segments (see figure 2 for non-white colored segments separated by white segments).

14. Considering **claim 17**, Howard shows in figures 1 and 2, an insert (22) to fit in a support tray (24) of the housing of the tray assembly (20) which is used for insertion into the optical inspection machine (10).

15. Regarding **claims 18 and 19**, Howard shows in figures 1-3,

- a. an opening (17, fig 1-2) into which a tray assembly (20) and the apparatus are retracted
- b. an inspection location (see fig. 3) within the opening for receiving the apparatus
- c. a light source (46, fig. 3) for illumination the apparatus when the apparatus is received in the inspection location, and
- d. a detector (56, fig. 3) for receiving light reflected off the apparatus from the light source.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. **Claims 8, 12-16, 20, 21 and 24-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Howard (EP Pub. # 0 837 320)**.

19. Considering **claim 8**, Howard discloses (col. 4, lines 15-21) and shows in figure 2, the insert (22) is secured within a housing (20) for allowing the insert to be illuminated by the readhead (34) of the optical inspection machine but fails to specifically disclose the housing includes a window.

However it would have been obvious to one having ordinary skill in the art to provide a window on the housing to allow for the readhead to illuminate the insert through the window since a window would provide closure to the housing that provides for a closed environment for the insert.

20. Considering **claims 12-14**, Howard discloses the colored segments can be of various colors, including: blue, red, green, black, or white but fails to specifically disclose the specific colors or orange, green, aqua and gray.

However it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the specific colors of orange, green, aqua and gray depending on the analyte to be measured and the wavelength employed by the spectrometer, since it has been held to be within the general skill of a worker in the art to select the color of the material on the basis of its suitability for the intended use as a matter of obvious design choice. Further, it has been held that a recitation with respect to the manner in which a claimed apparatus is indeed to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

21. Regarding **claims 15 and 16**, Howard discloses and shows in figures 1 and 2, the housing (20) of a tray assembly (channels 24 and 26) for guiding the apparatus into the optical inspection machine (10), so that the apparatus can be correctly oriented in the tray assembly but fails to specifically disclose orientation features and more specifically different size indents and bosses in order to mate the inspection machine with the housing of the tray assembly.

However as seen in figures 1 and 2, it would be an obvious matter of design choice to provide some type of orientation features to mate the housing of a tray assembly to the optical inspection machine in order to provide for alignment of the system and therefore to provide for accurate measurement and analysis of the inserts.

22. Regarding **claims 21 and 28**, Howard discloses (col. 4-12) inserting an apparatus (20) having a row of colored segments that simulate reagent pads containing known types of analytes at known concentrations (i.e., absorbent layers of material impregnated with reagents in specific locations referred to as test fields on the reagent test strip (22, fig. 2) that takes place as an indication of the presence and/or concentration of analyte in the test fluid, col. 4, lines 22-34), wherein the row of colored segments are positioned so that segments can be illuminated by the readhead (34, fig. 3) of the optical inspection machine (10, fig. 1), operating the optical inspection machine (operation of the optical inspection machine (10) is controlled by the computer program and executed by the microprocessor (202), col. 5, lines 4-8), but fails to specifically disclose comparing the results provided by the optical inspection machine to the known types and concentrations of analytes simulated by the row of colored segments and to repeat the steps above.

However it would have been well within the level of ordinary skill in the art to use the computer and microprocessor to perform such comparison of results and therefore would have at least been obvious to one having ordinary skill in the art at the time the invention was made to compare the results to known concentrations in order to provide for standardized results. It would have been further obvious to one having ordinary skill in the art at the time the invention was made to repeat the steps of determining the results, since it has been held that repeating steps of a method involves only routine skill in the art.

23. Considering **claims 24-27**, Howard discloses (col. 5, line 44 – col. 6, line 9) and shows in figure 2, the colored segments include non-white colored segments separated by white segments (see figure 2 for non-white colored segments separated by white segments). Howard also discloses the colored segments can be of various colors, including: blue, red, green, black, or white but fails to specifically disclose the specific colors or orange, green, aqua and gray.

However it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the specific colors of orange, green, aqua and gray depending on the analyte to be measured and the wavelength employed by the spectrometer, since it has been held to be within the general skill of a worker in the art to select the color of the material on the basis of its suitability for the intended use as a matter of obvious design choice. Further, it has been held that a recitation with respect to the manner in which a claimed apparatus is indeed to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

24. Considering **claims 29-30**, Howard shows in figure 2, a top piece (see fig. 1) for allowing the insert (22) to be illuminated by the readhead (34) of the optical inspection machine (10) and a bottom piece (see fig. 2) secured to the top piece (see side pieces of housing (20) in fig. 2) with the insert (20) secured between the top and bottom pieces, wherein the bottom pieces includes an end wall (see end pieces of housing (20) in fig. 2) and side walls extending toward the top piece and that correctly position the insert but fails to specifically disclose the window on the top piece and the bosses extending from opposite ends of the window.

However it would have been obvious to one having ordinary skill in the art to provide a window on the housing to allow for the readhead to illuminate the insert through the window since a window would provide closure to the housing that provides for a closed environment for the insert. Further, it would be an obvious matter of design choice to provide some type of orientation features (applicant's bosses) in order to provide for proper insertion of the housing into the optical system which would therefore provide for accurate measurement and analysis of the inserts.

25. **Claims 2-6 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Howard (EP Pub. # 0 837 320)** in view of **Gross et al. (U.S. Patent # 4,867,946)**.

26. Considering **claims 2, 4, 6 and 22**, Howard fails to specifically disclose offset parallel rows of indicators extending from ends of the row of colored segments.

In the same field of endeavor, Gross discloses (col. 1, line 53 – col. 2, line 64) and shows in figure 2, a device for evaluating test strips comprising offset parallel rows of black indicators (5) extending from the rows of colored segments (9), used to properly align the apparatus (i.e., position marks)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for black indicators on the test strips in order to easily align the test strips under the readhead for accurate measurements.

27. Regarding **claims 3 and 5**, the modified system of Howard fails to specifically disclose the indicators comprise bosses having flat top surfaces and that the indicators are square.

However, it would have been obvious matter of design choice to change the shape or the indicators such that the indicators have bosses with flat top surfaces or to be square since such a modifications to the indicators would have involved a mere change in shape and it appears that the invention would perform equally well without such a modification and would be well within the level of ordinary skill in the art. It would have been further obvious in order to provide for easier alignment within the optical inspection machine.

28. Considering **claim 20**, Howard fails to disclose a light source providing different wavelengths.

In the same field of endeavor, Gross discloses (col. 1, line 53 - col. 2, line 30) the use of different wavelengths to illuminate the test strip.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to illuminate using different wavelengths in order to adapt for the possibility of testing different analytes and therefore requiring different wavelengths which would provide for a more complete range of analysis capabilities for the analysis system.

29. **Claims 9, 10 and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Howard (EP Pub. # 0 837 320)** in view of **Matzinger et al. (U.S. Patent # 6,168,957)**.

30. Regarding **claim 9**, Howard fails to specifically disclose the insert is made from paper and the colored segments are printed ink.

However in the same field of endeavor, Matzinger discloses (col. 4, lines 38-41) the insert is made from paper.

It would have been obvious to one having ordinary skill in the art at the time the invention was made for the insert to be made of paper, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. It would have been further obvious to use paper as the material of choice for the insert to provide for a less expensive and disposable material for the insert.

31. Considering **claims 10 and 23**, Howard fails to disclose the colored segments are printed ink.

In the same field of endeavor, Matzinger discloses (col. 6, lines 46-57) the colored segments are applied via ink-jet printing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made for the colored segments to be printed ink, since it is easier to control the appropriate ratio of ink applied (col. 6, lines 46-57).

Conclusion

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara S. Pajoochi whose telephone number is 571-272-9785. The examiner can normally be reached on Monday - Thursday 7:30 a.m. - 4:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tarifur R. Chowdhury can be reached on 571-272-2287. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

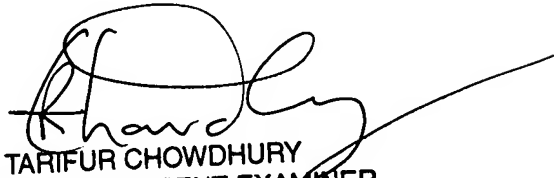
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TSP

Tara S. Pajoohi
Patent Examiner


TARIFUR CHOWDHURY
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